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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,080	10/23/2003	Richard L. Apodaca	PRD0025NP	8314

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EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,080	APODACA ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-68 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 46, and claims 1-42, 47-54, 68 wherein NR1R2 is pyrrolidine/piperidine, Q is piperidine, drawn to compound/composition wherein the core is three heterocyclic ring containing pyrrolidin/piperidine , classified in class 546, subclass 208.

II. Claims 43-45 and claims 1-42, 47-54, 68 wherein NR1R2 is pyrrolidin/piperidine, Q is other than piperidine, drawn to compound/composition wherein the core is three heterocyclic ring containing heterocycles and Q is not piperidine, classified in class various, subclass various depending on species election. If this group is elected, a further election of a single disclosed species is also required.

III. Claims 1-42, 47-54, 68, when NR1R2 is heterocyclic other than pyrrolidine/ piperidine and Q contains heterocyclic ring, drawn to compound/composition wherein the core is three heterocyclic ring, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required. Further restriction may be required.

IV. Claims 1-42, 47-54, 68, when NR1R2 is nonheterocyclic, drawn to compounds/ compositions wherein the core is a two heterocyclic ring, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required. Further restriction may be required.

V. Claims 1-42, 47-54, 68 wherein NR1R2 is nonheterocylic, Q is nonheterocyclic, drawn to compounds/compositions wherein the core is a single heterocyclic ring, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required. Further restriction may be required.

VI. Claims 56-58, drawn to method of inhibiting histamine receptor H3, classified in class various, subclass various depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment of a single disclosed pathology/disease is also required.

VII. Claims 59-60, drawn to method of inhibiting histamine receptor H1, classified in class various, subclass various depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment of a single disclosed pathology/disease is also required.

VIII. Claims 61-62, drawn to method of inhibiting histamine receptor H2, classified in class various, subclass various depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment of a single disclosed pathology/disease is also required.

IX. Claim 63, drawn to method of treating sleep/wake disorder etc., classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment of a single disclosed pathology/disease is also required.

X. Claim 64, drawn to method of treating ADHA, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment is also required.

XI. Claim 65, drawn to method of treating dementia, cognitive dysfunction etc., classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment of a single disclosed pathology/disease is also required.

XII. Claim 66, drawn to method of treating upper airway allergic response, nasal congestion or allergic rhinitis, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclose compound to be used for treatment of a single disclosed pathology/disease is also required.

XIII. Claims 55 and 67, drawn to material and method of employing PET imagine, classified in class 435, subclass various, depending on species election. If this

group is elected a single disclosed species of material for a specific single disclosed PET image is also required.

The inventions are distinct, each from the other because:

Groups I-V compounds are independent and distinct because each group differ from another in elements, bonding arrangements and chemical properties to such an extend that a reference anticipating any one of the groups would not necessarily imply unpatentability of another group. The "core" structure is so diverse that no substantial commonality in the structure can be identified to be responsible for the common utility. It is evidenced in the art that the compounds anticipating the single heterocyclic ring core i.e. group V compounds, has activity in treating tuberculosis, which is completely distinct from the instant claims (see US 2005/0222408 page 3 right column).

Inventions I-V and VI-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case method of treating airway disorder can be practice with another material different product such as deslaratadine (see US 4,659,716, claim 16).

Group I-XII and group XIII are unrelated inventions because the PET is not related to compound per se or method of using compound.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the groups/species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups/species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory of a Rejoinder

The following is a recitation of MPEP 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims, which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims, which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered. *Applicants are reminded of propriety of process of use claims in consideration of the "reach-trough" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease.*

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all of the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with MPEP 821.04 and In re Ochiai, 71 F. 3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 24, 2006

Celia Chang
Primary Examiner
Art Unit 1625